I. Amendments to the Claims:

This listing of claims will replace all prior versions of claims in the application.

Listing of Claims:

Claim 1. (Currently amended): A method of preparing a bioavailable sustained release tablet comprising:

combining (i) a medicament in amorphous form, and (ii) ~~a wetting agent and (iii)~~ a sustained release excipient to obtain a mixture; said sustained release excipient comprising a gelling agent, an ionizable gel strength enhancing agent, and an inert diluent, the ratio of inert diluent to gelling agent being from about 1:8 to about 8:1, said ionizable gel strength enhancing agent increasing the gel strength of a gel formed when said solid dosage form is exposed to environmental fluid, and said gelling agent comprising xanthan gum and locust bean gum in a ratio of from about 1:3 to about 3:1; wherein the medicament is rendered amorphous by a procedure selected from the group consisting of:

i) a fusion method;

ii) a coprecipitation or coevaportation method; and

iii) a melting-solvent method;

thereafter drying and milling said mixture to obtain a sustained release tablet; applying a support platform to said tablet; and

forming said sustained release product into orally administrable unit doses.

Claim 2. (Original): The method of claim 1, wherein the medicament has an aqueous solubility of less than 10 g/liter.

Claim 3. (Cancelled)

Claim 4. (Original): The method of claim 1, wherein said medicament is selected from the group consisting of nifedipine, nimodipine, nivadipine, nitrendipine, nisolidipine, niludipine, nicardipine and felodipine.

Claim 5. (Previously presented): The method of claim 4, wherein said medicament is nifedipine.

Claim 6. (Cancelled)

Claim 7. (Previously presented): The method of claim 1, further comprising adding an amount of a pharmaceutically acceptable hydrophobic material effective to slow the hydration of the gelling agent when said solid dosage form is exposed to gastrointestinal fluid.

Claim 8. (Cancelled)

Claim 9. (Previously presented): The method of claim 7, wherein said mixture of, gelling agent, ionizable gel strength enhancing agent, hydrophobic material and inert diluent are premanufactured as a sustained release excipient.

Claim 10. (Previously presented): The method of claim 7, wherein said hydrophobic material is added to the sustained release excipient prior to the medicament, wetting agent, and sustained release excipient.

Claims 11 -13. (Cancelled)

Claim 14. (Previously presented): The method of claim 7, wherein said hydrophobic material is selected from the group consisting of alkylcellulose, hydrophobic cellulosic materials, polymers or copolymers derived from acrylic or methacrylic acid esters, copolymers of acrylic and methacrylic acid esters, zein, waxes, shellac, and hydrogenated vegetable oils.

Claim 15. (Previously presented): The method of claim 1, wherein said ionizable gel strength enhancing agent is selected from the group consisting of monovalent, divalent and multivalent organic or inorganic salts and mixture thereof.

Claim 16. (Previously presented): The method of claim 1, wherein said ionizable gel strength enhancing agent is selected from the group consisting of an alkali metal, alkali metal chloride, alkali metal borate, alkali metal bromide alkali metal citrate, alkali metal acetate, alkali metal lactate, alkaline earth metal sulfate, alkaline earth metal chloride, alkaline earth metal borate, alkaline earth metal bromide, alkaline earth metal citrate, alkaline earth metal acetate, alkaline earth metal lactate and mixtures thereof.

Claim 17. (Cancelled)

Claim 18. (Previously presented): A method of treating a patient comprising administering a tablet prepared according to claim 1, to a patient in need of antihypertensive treatment.

Claim 19. (Previously presented): The method of claim 1, wherein said support platform comprises a polymeric material insoluble in aqueous liquids.

Claim 20. (Previously presented): The method of claim 19, wherein said polymeric material is selected from the group consisting of derivatives of acrylic acid, celluloses and derivatives thereof, polyvinylalcohols, and the like.

Claim 21. (Previously presented): The method of claim 20, wherein said polymeric material is ethylcellulose.

Claim 22. (Previously presented): The method of claim 19, wherein said support platform is compression coated onto part of a surface of said tablet.

Claim 23. (Previously presented): The method of claim 22, wherein said support platform has a thickness of about 2mm.

Claim 24. (Previously presented): The method of claim 19, wherein said polymeric material is spray dried onto part of the surface of said tablet.

Claim 25. (Previously presented): The method of claim 19, wherein said tablet is immersed in a solution of a polymeric material to form said support platform.

Claim 26. (Previously presented): The method of claim 24, wherein said support platform has a thickness of about 10μm.

Claim 27. (Previously presented): The method of claim 25, wherein said support platform has a thickness of about 10μm.

Claim 28. (Previously presented): The method of claim 1, wherein the ratio of said medicament to said gelling agent is from about 1:3 to about 1:8.

Claim 29. (Previously presented): The method of claim 14, wherein the pharmaceutically acceptable hydrophobic material is included in the sustained release excipient in an amount from about 1 to about 20 percent by weight.

Claim 30. (Previously presented): The method of claim 29, wherein the hydrophobic material is ethyl cellulose.

Claim 31. (New) The method of claim 1, wherein said fusion method comprises:

a) heating a physical mixture of the medicament and a carrier to a fluid state;
b) cooling the fluid medicament-carrier to room temperature to obtain a solid dispersion.

Claim 32. (New) The method of claim 1, wherein said coprecipitation or coevaporation method comprises:

a) dissolving the medicament and a carrier in a volatile organic solvent; and

b) evaporating the solvent to obtain a solid dispersion.

Claim 33. (New) The method of claim 1, wherein said melting solvent method comprises:

a) dissolving the medicament with a co-solvent to form a solution;

b) mixing the solution with a molten carrier; and

c) cooling the resulting solution to room temperature to obtain a solid dispersion.

Claim 34. (New) The method of claim 31, wherein the carrier is a pharmaceutically acceptable wetting agent.

Claim 35. (New) The method of claim 34, wherein the wetting agent is a polyethylene glycol (PEG) material.

Claim 36. (New) The method of claim 31, wherein the carrier is a mixed surfactant/wetting agent system.

Claim 37. (New) The method of claim 36, wherein the mixed surfactant/wetting agent system is selected from the group consisting of sodium lauryl sulfate/solid polyethylene glycol 6000 and sodium lauryl sulfate/solid polyethylene glycol 6000/ stearic acid.

Claim 38. (New) The method of claim 34, wherein the wetting agent is included in an amount from about 2% to about 20% by weight of the final product.

Claim 39. (New) The method of claim 32, wherein the carrier is a pharmaceutically acceptable wetting agent.

Claim 40. (New) The method of claim 39, wherein the wetting agent is a polyethylene glycol (PEG) material.

Claim 41. (New) The method of claim 33, wherein the carrier is a pharmaceutically acceptable wetting agent.

Claim 42. (New) The method of claim 41, wherein the wetting agent is a polyethylene glycol (PEG) material.

II. Remarks and Arguments:

Claims 1, 2, 4, 5, 7, 9-10, 14-16, and 18-42 are pending. Claims 1 has been amended; and claims 31-42 have been added as new. Support for these amendments can be found in the specification at page 9, lines 15-29; page 10, lines 1-16; and page 11, lines 17-23. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

A. Rejection Under 35 U.S.C. § 103(a):

In the Final Office Action, mailed October 2, 2006, the Examiner maintained his rejection of claims 1-7, 9, 10, 14-16 and 18-30 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,128,143 to Baichwal et. al. (hereinafter "the '143 patent") in view of U.S. Patent No. 5,472,712 to Oshlack et. al. (hereinafter "the '712 patent") and in further view of U.S. Patent No. 4,939,177 to Colombo (hereinafter "the '177 patent"). The Examiner stated that:

> "All of the patents are related in that they all disclose controlled or sustained release formulations. Baichwal discloses a tablet that comprises all of applicants claimed invention except for the use of a solid support, while Oshlack discloses a substrate that can be a tablet that is coated with a hydrophobic polymer (ethylcellulose) and Colombo discloses a support platform applied to a deposit core..., thus by combining the disclosures above one skilled in the art could make, on their own, the same invention as applicants... It would have been obvious to combine the above documents because there is always motivation to enhance the controlled release of a medicament, so that one skilled in the art could foresee that by combining the controlled release tablet in Baichwal and the controlled release coatings or solid support in Oshlack and Colombo the release rate of the dosage form could be further enhanced or modified."

Applicants responded to the Examiner's rejection by stating *inter alia* that none of the cited references teach or suggest a medicament in amorphous form. In the subsequent Advisory Action mailed February 9, 2007, the Examiner stated:

> "Applicants argue that none of the references including the '143 [U.S. 5,128,143 to Baichwal, et al.] teach the use of an amorphous medicament, the examiner

> does not find this persuasive. Clearly the '143 patent discloses that all or part of the excipient may be subjected to a wet granulation with the active ingredient and thereafter tableted. See col 9 line 1-4. This treatment would render the medicament into an amorphous form."

This rejection is respectfully traversed.

Independent claim 1 of the present invention has been amended to recite:

1. Claim 1. (Currently amended): A method of preparing a bioavailable sustained release tablet comprising:

combining (i) a medicament in amorphous form, and (ii) a sustained release excipient to obtain a mixture; said sustained release excipient comprising a gelling agent, an ionizable gel strength enhancing agent, and an inert diluent, the ratio of inert diluent to gelling agent being from about 1:8 to about 8:1, said ionizable gel strength enhancing agent increasing the gel strength of a gel formed when said solid dosage form is exposed to environmental fluid, and said gelling agent comprising xanthan gum and locust bean gum in a ratio of from about 1:3 to about 3:1; wherein the medicament is rendered amorphous by a procedure selected from the group consisting of:

i) a fusion method;
ii) a coprecipitation or coevaportation method; and
iii) a melting-solvent method;

thereafter drying and milling said mixture to obtain a sustained release tablet;

applying a support platform to said tablet; and

forming said sustained release product into orally administrable unit doses.

The medicament utilized in the present invention can be rendered into its amorphous form by various methods, such as by dispersing an insoluble medicament into a solid, water soluble carrier to form a solution or dispersion that is thereafter rendered solid to form a "solid solution" or a "solid dispersion" that provides improved solubility characteristics (Id. at page 9, lines 15-20). Other methods of rendering the medicament into amorphous form include manufacturing solid solutions or dispersions by i) a fusion method, which involves heating a physical mixture of medicament and carrier to a fluid state and subsequently cooling to room temperature; ii) co-precipitation or co-evaporation conducted by dissolving a medicament and carrier in a volatile organic solvent, followed by evaporation of the solvent, leaving a dispersion as a residue; and iii) a melting-solvent method conducted by dissolving medicament within a cosolvent, and mixing the resulting

solutions with a molten carrier, followed by cooling of the fluid to room temperature (Id. at page 10, lines 1-8), as claimed in independent claim 1 of the present invention.

Applicants respectfully submit that the '143 patent does not teach or suggest the use of a medicament in amorphous form as claimed in the present invention. The '143 patent describes an excipient composition that may be mixed with a wide range of medicaments and directly compressed into a solid dosage form, without the aid of the usual pharmaceutical dry or wet binders, filers, disintegrants, and glidants (See: the '143 patent, col. 5, lines 57-62). The medicament utilized in the '143 patent is added directly to the excipient described therein via dry or wet granulation techniques (See: Examples 2-57). Nowhere does the '143 patent teach or suggest utilizing a medicament in amorphous form, wherein the medicament is rendered amorphous by a procedure selected from the group consisting of i) a fusion method; ii) a coprecipitation or coevaportation method; and iii) a melting-solvent method, as claimed in independent claim 1 of the present invention.

The '712 patent is directed to controlled release substrates, wherein an active agent substrate(s) (e.g., tablet, spheroid (bead), microsphere, seed, pellet, or other multi-particulate system) is/are coated with an aqueous dispersion of a hydrophobic polymer, e.g., ethylcellulose, wherein the controlled release is caused by a coating of the substrate with the hydrophobic polymer (See: '712 patent at col. 3, lines 24-27). Nowhere does the '712 patent teach or suggest utilizing a medicament in amorphous form, wherein the medicament is rendered amorphous by a procedure selected from the group consisting of i) a fusion method; ii) a coprecipitation or coevaportation method; and iii) a melting-solvent method, as claimed in independent claim 1 of the present invention.

The '177 patent is directed to a controlled release system comprising a deposit-core containing an active agent having a defined geometric form; and a support-platform applied to the deposit core, the deposit core containing mixed with the active agent a polymeric material having a high degree of swelling on contact with water or a aqueous

liquid, a gullible polymeric material being replaceable by a single polymeric material having both swelling and gelling properties, as well as other adjuvants, the support platform consisting of a polymeric material insoluble in aqueous liquids and partially coating the deposit core. Nowhere does the '177 patent teach or suggest utilizing a medicament in amorphous form, wherein the medicament is rendered amorphous by a procedure selected from the group consisting of i) a fusion method; ii) a coprecipitation or coevaportation method; and iii) a melting-solvent method as claimed in independent claim 1 of the present invention.

In view of the arguments provided above, it is respectfully submitted that neither the '712 patent or the '177 patent can cure the deficiencies of the '143 patent. Therefore, independent claim 1 of the present invention is not obvious over the '143 patent in view of the '712 patent or the '177 patent. As claims 2, 4, 5, 7, 9-10, 14-16, and 18-42 depend from claim 1, these claims are also not obvious over the '143 patent in view of the '712 patent or the '177 patent.

Applicants respectfully request that the Examiner's rejection be removed.

B. <u>Double Patenting Rejection:</u>

In the Final Office Action, the Examiner rejected claims 1-7, 9, and 10, 14-16 and 18-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. 6,048,548 in view of U.S. 4,839,177.

The Examiner also rejected claims 1-7, 9, 10, 14-16 and 18-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. 6,709,677 in view of U.S. 4,829,177 (Columbo).

Applicants respectfully submit that upon receipt of a Notice of Allowance indicating the present claims are otherwise allowable, the filing of a terminal disclaimer will be considered.